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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,075	02/19/2004	Sean D. Monahan	25772 US2	4417
83890	7590	07/16/2010	EXAMINER	
ROCHE MADISON INC. 465 Science Drive Suite C MADISON, WI 53711			CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER
			1635	
			MAIL DATE	DELIVERY MODE
			07/16/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/782,075	MONAHAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	KIMBERLY CHONG	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 May 2010.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,4-6,10,13,14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,4-6,10,13 and 14 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/31/2010</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response 05/11/2010 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 02/18/2010 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 05/11/2010, claims 1, 4-6, 10, 13 and 14 are pending in the application.

### ***Response to Declaration***

The declaration filed on 05/11/2010 under 37 CFR 1.132 is sufficient to overcome the rejection of claims 1, 5, 6, 10 and 13-14 rejected under 35 U.S.C. 102(e) as being anticipated by Lewis et al. (US 2003/0143204 of record PTO Form 892 mailed 12/31/2007) and further evidenced by Thierry et al. (US 6,110,490) and claims 1, 4-6, 10, 13 and 14 under 35 U.S.C. 103(a) as being obvious over Lewis et al. (US 2003/0143204 of record PTO Form 892 mailed 12/31/2007), Manoharan, M. (Biochimica et Biophysica Acta 1489, 1999: 117-130 of record PTO Form 892 mailed 12/31/2007) and further evidenced by Thierry et al. (US 6,110,490).

***Claim Objections – necessitated by claim amendments***

Claim 5 is objected to because of the following informalities: claim 5 recites the limitation “wherein the labile is selected...”. The sentence appears to be incomplete and should recite the “labile bond”. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

***Necessitated by claim amendments***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-6, 10 and 13-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1, 4-6, 10 and 13-14 are drawn to a composition comprising an RNA consisting of “at least one hydrophobic group having one to twenty carbon atoms” and wherein “transfection reagent is enhanced via hydrophobic interactions between the hydrophobic group linked to the RNA with a hydrophobic part of the amphipathic transfection reagent”.

The specification does not disclose or contemplate a RNA consisting of a hydrophobic group having a range of one to twenty carbon atoms. The specification

does exemplify specific hydrophobic groups having carbon atoms within that range but there is not support for the claimed range.

Further, the specification does not contemplate the limitation wherein the hydrophobic group linked to the RNA binds to the hydrophobic group of the transfection reagent.

If Applicant believes that such support is present in the specification and claimed priority documents, Applicant should point, with particularity, to where such support is to be found.

***Response to Applicant's Arguments***

***Claim Rejections - 35 USC § 102 - maintained***

The rejection of claims 1, 4-6, 10 and 13-14 under 35 U.S.C. 102(e) as being anticipated by Fosnaugh et al. (US 2003/0143732 of record PTO Form 892 mailed 12/31/2007) as evidenced by Thierry et al. (US 6,110,490) is maintained for the reasons of record.

Applicant's arguments filed 05/11/2010 have been fully considered but they are not persuasive. Applicant submits the Examiner's interpretation of enhance is excessively broad and expands the definition beyond the ordinary and customary meaning beyond the field and the instant specification. The Examiners interpretation was not broad because the term "enhanced" was interpreted to mean the interaction of a siRNA molecule comprising a hydrophobic group with a transfection agent such that the siRNA is capable of entering a cell. Thus based on the description of a hydrophobic modification of an siRNA from the specification and interpretation of the claim

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limitations, a siRNA which consists of any hydrophobic modification would allow interaction of the siRNA with the transfection agent and therefore would alter i.e. enhance the interaction of a siRNA with a transfection agent. Thus because Fosnaugh et al. teach conjugates comprising siRNA and functional groups that are complexed with liposomes and because Thierry et al. teach liposomal complexes comprising oligonucleotides are formed by hydrophobic interactions, Fosnaugh et al. anticipates the instant claims.

Applicant further argues Fosnaugh et al. teach a wide range of modifications and delivery vehicles and do not provide any clear guidance as to which modifications, delivery vehicles or combinations possess the desired properties. It is not clear which desired properties the Applicant is referring to. The claims are drawn to a composition comprising a modified RNA molecule consisting of a hydrophobic group and a transfection reagent wherein the association of the RNA is enhanced via a hydrophobic interaction between the group and the transfection reagent. As stated previously and reiterated above, because Fosnaugh et al. teach conjugates comprising siRNA and functional groups that are complexed with liposomes and because Thierry et al. teach liposomal complexes comprising oligonucleotides are formed by hydrophobic interactions, Fosnaugh et al. anticipates the instant claims.

Applicant argues Fosnaugh et al. do not teach a hydrophobic modification that enhances the interaction of the RNA with the transfection reagent. As discussed previously, a siRNA which consists of any hydrophobic modification would allow interaction of the siRNA with the transfection agent and therefore would alter i.e.

enhance the interaction of a siRNA with a transfection agent which would be an inherent property. Because the term "enhanced" is not defined in the instant specification and Applicant has not shown specifically how the hydrophobic group enhances this interaction, the arguments are not persuasive. Further the instant claims broadly recite at least one hydrophobic group which could be a lipid and do not exemplify which hydrophobic group has this property of enhancing the interaction with a transfection reagent. One of ordinary skill in the art based on Fosnaugh et al. would attach a hydrophobic group such as a lipid to a RNA molecule because this modification was known to enhance the properties of the RNA molecule.

The specification discloses that RNA molecules with an attached hydrophobic group can alter the interaction of the RNA with the transfection reagent thus because Fosnaugh et al. teach conjugates comprising siRNA and functional groups that are complexed with liposomes and the functional groups such as lipids have the inherent property of altering the interaction between the lipid and a transfection reagent such as liposomes, Fosnaugh et al. anticipates the instant claims.

***Claim Rejections - 35 USC § 103 - maintained***

The rejection of claims 1, 4-6, 10, 13 and 14 under 35 U.S.C. 103(a) as being obvious over Fosnaugh et al. (US 2003/0143732 of record PTO Form 892 mailed 12/31/2007), Manoharan, M. (*Biochimica et Biophysica Acta* 1489, 1999: 117-130 of record PTO Form 892 mailed 12/31/2007) and further evidenced by Thierry et al. (US 6,110,490) is maintained for the reasons of record.

Applicant states that the amendments and arguments made above in the response to the 102 rejection are sufficient to overcome the 103 rejections. Response to Applicant's arguments are addressed above and do not overcome the 102 rejections of record and therefore do not overcome the 103 rejection.

Thus, the rejection of record is maintained.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact Christopher Low at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/  
Primary Examiner  
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